SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ascorbic Acid Tablets BP 500mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active	mg / tablet
Ascorbic Acid BP	500.00 mg

3 PHARMACEUTICAL FORM

Uncoated tablets for oral administration.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For use in treating vitamin C deficiency including the treatment and prevention of scurvy.

4.2 Posology and method of administration

Adults, the elderly and children over 12 years:
One to five tablets daily in divided doses.

Children aged 4 – 12 years:
Half to two and a half tablets daily in divided doses.

Note: As the dietary intake of vitamin C may be less in the elderly, they are at greater risk of being deficient in this vitamin.

4.3 Contraindications

Ascorbic acid supplements should not be given to patients with hyperoxaluria.

4.4 Special warnings and precautions for use

Vitamin C may interfere with tests and assays for urinary glucose, giving false negative results with methods utilising glucose oxidase with indicator (e.g. Labstix, Testape) and false positive results with neocuproin methods. Estimation of uric acid by phosphotungstate or by uricase with copper reduction and measurement of creatinine in non-deproteinised serum may also be affected. High doses of vitamin C may give false-negative readings in faecal occult blood tests.

4.5 Interaction with other medicinal products and other forms of interaction

Vitamin C increases the renal excretion of amphetamine. The plasma concentration of ascorbate is decreased by smoking and oral contraceptives. Massive doses of vitamin C may reduce the response of some patients on long term therapy with oral anticoagulants. Vitamin C increases the absorption of iron.

4.6 Fertility, Pregnancy and lactation

There is inadequate evidence of the safety of ascorbic acid in human pregnancy but it has been in wide use for many years without apparent ill consequences, animal studies having shown no hazard. Ascorbic acid crosses the placenta. The established medical principal of only administering drugs in early pregnancy when considered absolutely necessary should be observed. Ascorbic acid is excreted in breast milk but there is no evidence of any hazard.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Large doses of ascorbic acid may cause diarrhoea. Patients known to be at risk of hyperoxaluria should not ingest ascorbic acid in doses exceeding 1 gram daily, as there may be increased urinary oxalate excretion. However, such a risk has not been demonstrated in normal, non-hyperoxaluric individuals. Ascorbic acid has been implicated in precipitating haemolytic anaemia in certain individuals with a deficiency of glucose-6-phophate dehydrogenase. Increased intake of ascorbic acid over a prolonged period may result in an increase in renal clearance of ascorbic acid, and deficiency may result if the intake is reduced or withdrawn rapidly. Doses of more than 600mg daily have a diuretic effect.

4.9 Overdose

At doses of over 3 grams per day unabsorbed ascorbic acid is chiefly excreted un-metabolised in the faeces. Absorbed ascorbic acid additional to the body's needs is rapidly eliminated. Large doses of ascorbic acid may cause diarrhoea and the formation of renal oxylate calculi. Symptomatic treatment may be required.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ascorbic acid coupled with dehydroascorbic acid to which it is reversibly oxidised, has a variety of functions in cellular oxidation processes. Vitamin C is required in several important hydroxylations, including the conversion of proline to hydroxyproline (and thus in collagen formation e.g. for intercellular substances during wound healing); the formation of the neurotransmitters 5-hydroxytryptamine from tryptophan and noradrenaline from dopamine; and the biosynthesis of carnitine from lysine and methionine. Vitamin C appears to have an important role in metal ion metabolism, including the gastrointestinal absorption of iron and its transport between plasma and storage organs. There is also evidence that vitamin C is required for normal leukocyte function and that it participates in the detoxification of numerous foreign substances by the hepatic microsomal system.

Deficiency in vitamin C leads to scurvy, which may be manifested by weakness, fatigue, dyspnoea, aching bones, perifollicular hyperkeratoses, petechiae and ecchymoses, swelling and bleeding of gums, hypochromic anaemia and other haematopoietic disorders, together with reduced resistance to infection (and impaired wound healing).

5.2 Pharmacokinetic properties

Ascorbic acid is well absorbed from the gastro-intestinal tract, and is widely distributed to all tissues. Body stores of ascorbic acid normally are about 1.5 grams. The concentration is higher in leukocytes and platelets than in erythrocytes and plasma. Ascorbic acid additional to the body's needs (generally amounts above 200mg daily) is rapidly eliminated; unmetabolised vitamin C and its inactive metabolic products are chiefly excreted in the urine. The amount of ascorbic acid excreted unchanged in the urine is dose-dependent and may be accompanied by mild diuresis.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose BP, potato starch BP, syrup BP, talc BP, stearic acid BPC, microcrystalline cellulose BP.

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Tablets should be stored in a dry place below 25°C

6.5 Nature and contents of container

The tablets are available in Securitainers or Tampertainers in packs 28, 50, 100 or 500 tablets. Specification for Securitainers and Tampertainers: High density polypropylene containers with low density polyethylene caps.

The tablets are also available in blister packs of 28 tablets.

6.6 Special precautions for disposal

Always read instructions on the label and the Patient Information Leaflet (PIL) enclosed.
Keep all medicines out of the reach of children.
Do not use after the expiry date.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

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27/09/2005

10 DATE OF REVISION OF THE TEXT

06/02/2018